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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,670	07/13/2001	Phillip D. Purdy	UTSD:798US	4825

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/905,670

Applicant(s)

PURDY, PHILLIP D.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,14-16 and 29-63 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 64,66,68 and 69 is/are allowed.
- 6) ☒ Claim(s) 1-3,7,8,11,13,21,22,24,27,28,65 and 67 is/are rejected.
- 7) ☒ Claim(s) 4-6,12,17-20,23,25 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendments submitted 8 March 2007.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1,7,11,13,21,24,27,28,65 are rejected under 35 U.S.C. 102(b) as being anticipated by AEBISCHER (US 5,487,739).

Regarding claim 1, Aebischer teaches a method of navigating the subarachnoid space (Fig 2J, 116) comprising: percutaneously introducing a sufficiently flexible guidewire (102) into the spinal subarachnoid space at an entry location (between L3 and L4); introducing a device over the guidewire (cannula 20), the device having a first passageway to slidably receive, and work with, at least the guidewire, and the guidewire being positioned in the passageway (See Cols 9-11, description of Figs 2A-2J); and advancing the device over the guidewire and within the spinal subarachnoid space at least more than 10 centimeters from the entry location (to site 12'). Regarding the distance to the treatment site, Aebischer discloses the use of a 4" (10.2 cm) Tuohy needle to introduce the guidewire and a 31" long guidewire. It is further disclosed that a tether (44) is 8-10cm long. As can be seen, especially in Figure 4, the tether extends from a point distal of the entry location to the treatment location, therefore requiring the guidewire to be advanced at least more than 10cm.

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Regarding claim 7, the device (20) includes a second passageway (lumen of the dilator 104), configured to slidably receive and work with the guidewire (Fig 2E)

Regarding claim 11, a cross-section taken at the point where clip 60 crimps the device would be non-circular (Fig 3A).

Regarding claim 13, medication (pellet 80A) is delivered to an intracranial subarachnoid space.

Regarding claims 21 and 65, a penetration apparatus (100) is inserted through the first passageway of cannula (20) with an inner puncture element (100B) which is used to puncture the pia matter (Fig 4).

Regarding claim 24, the position of the device is monitored via radio-opaque material (Col 5 1st full paragraph).

Regarding claim 27, material (pellet 80) is introduced and can be placed near a cranial nerve in order to treat a neurological condition.

Regarding claim 28, the material can be genetic (cells 26).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebischer in view of MICHAELI (US 6,328,694).

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Aebischer teaches a method of inserting a device into the subarachnoid space and delivering a medication thereto. Aebischer does not teach removing a portion of the brain. However, in the placement of the dilator, catheter, and capsule, it would seem that a portion of the brain tissue would be removed. In light of Aebischer's silence on this point, Michaeli is referenced. Micheali discusses a method of performing brain surgery wherein a portion of the brain is removed (Col 2, lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Aebischer to include the explicit teachings of removing brain tissue as taught by Michaeli in order to increase the chance of recovery for the rest of the brain and improve effectiveness of treatment.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aebischer.

Aebischer does not explicitly teach the flushing of cerebrospinal fluid to remove blood, but does teach that a sample of fluid can be removed through the guidance needle and tested for the presence of CSF. It would have been obvious to one of ordinary skill in the art at the time the invention was made to remove any blood present in the removed CSF in order to collect a more pure sample for testing.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aebischer in view of PUTZ (US 6,004,262).

Aebischer discloses a cannula inserted into the subarachnoid space and a dilator inserted into the space. Aebischer does not teach the use of an endoscope inserted into the dilator or cannula. Putz discloses the use of an endoscope to assist in navigation

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through the subarachnoid space (Col 3 line 33- Col 5 line 30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert an endoscope into the channel of the dilator of Aebischer in order to improve visualization of the surgical site and avoid errors in surgery.

6. Claims 25,26, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebischer in view of HOFMANN (US 6,330,466

Aebischer discloses a cannula inserted into the subarachnoid space and a dilator inserted into the space. Aebischer does not teach the use of an electrode being placed near brain tissue. Aebischer's device is perfectly capable of inserting an electrode near brain tissue. Hofmann teaches that it is well known in the art to place electrodes near the brain for the purpose of stimulating or recording. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the insertion procedure of Aebischer in order to insert the electrode of Hofmann near the brain tissue in order to provide treatment to a patient.

Allowable Subject Matter

7. Claims 64,66,68-69 are allowed.

8. Claims 4-6,12,17-20,23,25, and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments filed 8 March 2007 have been fully considered but they are not persuasive.

Aebischer:

Claim 1: Applicant has argued that Aebischer does not show advancing a guidewire in another direction beyond the distal end of the introducer. This is not persuasive because "another" is broadly defined as a different one of the same group (Dictionary.com), and a group can have duplicate members. Therefore, another does not have to be interpreted as different. Furthermore, the guidewire is sufficiently flexible to be direction in a different direction. See also Fig 2J.

Claim 65: First, Aebischer shows a percutaneous introduction in Fig 2J (through the spinal cord). Second, the applicant has not claimed that the steps of claim 65 must be performed in a certain order. Aebischer discloses the steps, merely in a different order than the applicant is arguing. Without claiming the order of the steps, this argument is not persuasive.

Claims 2,3,22,8 (Putz), 25,26: Applicant has not made arguments specifically addressing the rejection of the dependent claims, only the independent claims.

Aebischer in view of Hofmann:

Claim 67: Aebischer shows a percutaneous introduction in Fig 2J (through the spinal cord).

10. Applicant's arguments, see remarks page 17-18, with respect to Carroll have been fully considered and are persuasive. The rejection of claims 1,4,12,17,19 and 20 over Carroll has been withdrawn.

11. Applicant's arguments, see remarks page 18-19, with respect to Barbut have been fully considered and are persuasive. The rejection of claims 5,6,68, and 69 is withdrawn.

12. Applicant's arguments, see remarks page 20, with respect to Aebischer in view of Keep have been fully considered and are persuasive. The rejection of claims 8 and 64 is withdrawn.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*Ernesto
Marchillo
3/20/04*

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons